UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**Civil Action No. 3:16-md-2738-FLW-LHG**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DEFENDANTS GYNECOLOGY-ONCOLOGY EXPERTS DR. CHERYL SAENZ AND DR. KEVIN HOLCOMB

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The Plaintiffs' Steering Committee ("PSC") respectfully submits this motion to exclude the opinions and testimony of Johnson & Johnson's and Johnson & Johnson Consumer Inc.'s (collectively "J&J") gynecologic oncology experts, Dr. Cheryl Saenz and Dr. Kevin Holcomb, pursuant to Federal Rule of Evidence 104 (a), 702, 703 and 403.

I. INTRODUCTION AND SUMMARY

The opinions of Dr. Saenz and Dr. Holcomb are based on a flawed methodology that is contrary to widely accepted principles of interpreting epidemiology and the standards for proving a biologically plausible mechanism.

Under the standards articulated by the United States Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1983), the burden is on J&J as the party offering Drs. Saenz and Holcomb to demonstrate that both experts have used a reliable scientific method to reach their opinions. J&J has failed to meet its burden[1]:

- *First,* Drs. Saenz and Holcomb automatically value cohort studies above all other epidemiology, while improperly ignoring the totality of the evidence.
- *Second,* they erroneously dismiss the epidemiological studies that are unfavorable to their opinions based on a flawed understanding of statistical significance.

[1] *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999).

- *Third,* their dismissal of case-control studies based on recall bias is not based on sound methodology.

- *Fourth*, their opinions on biological plausibility are based on an incorrect standard of proof and ignore the totality of evidence.

- *Lastly,* Dr. Saenz's critiques of Dr. Smith-Bindman's epidemiological review should be excluded because Dr. Saenz lacks the basic qualifications to critique Dr. Smith-Bindman's epidemiological assessment and her testimony in this regard would not be helpful to the jury.

II. LEGAL STANDARD

The PSC incorporates the legal standard set forth in *The Plaintiffs' Steering Committee's Omnibus Memorandum of Law Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation* ("*Omnibus Brief*"), and supplements it as set forth herein.

III. OVERVIEW OF THE GYNECOLOGIC ONCOLOGY SPECIALTY AND RELEVANCE TO THIS LITIGATION

A gynecologic ("GYN") oncologist is a physician that specializes in the diagnosis and treatment of female reproductive cancers, including cancers of the ovary, uterus, cervix and vulva, and is responsible for all medical and surgical aspects of the patient's care. GYN oncologists have completed residencies in obstetrics and gynecology, and training through a gynecologic oncology fellowship. As part of patient care, GYN oncologists also evaluate whether a patient is at high risk for gynecologic cancers due to the patient's personal and family history.

In general, a GYN oncologist is qualified to opine on the following issues related to this action: 1) the causes and risk factors of ovarian cancer; 2) the increased risk of ovarian cancer with genital talcum powder use; 3) the migration or transport of particles through the female reproductive tract; and 4) the biologic mechanism involved in the pathogenesis of ovarian cancer.

IV. OVERVIEW OF J&J'S DESIGNATED GYN ONCOLOGISTS

J&J designated two GYN oncologists for purposes of general causation: Dr. Cheryl Saenz and Dr. Kevin Holcomb.

A. Dr. Cheryl Saenz

Dr. Saenz is board certified in gynecologic oncology and Obstetrics and Gynecology.[2] Dr. Saenz has been an physician at the University of California, San Diego (UCSD) Health System for over 20 years and is currently a clinical professor of gynecologic oncology in the Department of Obstetrics, Gynecology and Reproductive Sciences at the UCSD.[3] She currently cares for 40-50 patients a week and operates on 4-5 patients a week, most of which are women with a known gynecologic malignancy.[4]

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[2] *See* March 13, 2019 Deposition of Cheryl Saenz, M.D. ("Saenz Dep.) at 14:10-15, attached hereto as **Exhibit A.**

[3] *See* Expert Report of Cheryl Christine Saenz, MD for General Causation *Daubert* Hearing, dated Feb. 25, 2019 ("Saenz Report") at 1, attached hereto as **Exhibit B.**

[4] Saenz Report at 1.

Dr. Saenz is not an epidemiologist, does not have a degree in epidemiology, and is not an expert in asbestos.[5] She defers to other experts on "the chemical composition" of talcum powder, including the presence of heavy metals, fragrances, fibrous talc, and asbestos.[6] Dr. Saenz has no opinion on whether fragrances or heavy metals in the talcum powder products can cause ovarian cancer.[7] She also "doesn't have an opinion that [asbestos] does or that it does not" act as a risk factor for epithelial ovarian cancer. (Saenz Dep. at 152:3-12 ("Q. In your opinion, is asbestos a risk factor for epithelial ovarian cancer? A. Again, I don't think that's a yes or no answer, because I think the literature is somewhat inconsistent on that particular topic. Q. So you don't have that opinion? A. I don't have an opinion that it does or that it does not, correct.")).

B. Dr. Kevin Holcomb

Dr. Holcomb is a practicing GYN oncologist at Weill Cornell Medical Center-New York Presbyterian Hospital and the Director of Gynecologic Oncology.[8] Since the early 2000s, he has performed approximately 200-225 surgeries per year and

[5] Saenz Dep. at 129:8-11, 347:1-3.

[6] *Id.* at 65:20-68:17.

[7] *Id.* at 151:8-17.

[8] *See* March 27, 2019 Deposition of Kevin Holcomb, M.D. ("Holcomb Dep.") at 12:10-18; 300:23-301:17, attached hereto as **Exhibit C**. *See also* February 25, 2019 Expert Report of Kevin Holcomb, M.D., FACOG for General Causation *Daubert* Hearing ("Holcomb Report") at 2, attached hereto as **Exhibit D.**

treats approximately 20 new ovarian cancer patients a year.[9] Dr. Holcomb is not an epidemiologist, does not have a degree in epidemiology, and is not an expert in asbestos.[10] Dr. Holcomb has no opinions on whether J&J's talcum powder products contain carcinogenic fragrances, heavy metals, fibrous talc, or asbestos.[11]

C. Summary of the opinions of Drs. Saenz and Holcomb

Coincidentally, Drs. Saenz and Holcomb provide the same four general opinions regarding general causation: (1) there are known factors that increase or decrease the risk of the development of ovarian cancer;[12] (2) the epidemiological data does not demonstrate genital talcum powder use is a risk factor for the development of ovarian cancer;[13] (3) talcum powder cannot migrate from the perineum to the fallopian tubes or ovaries;[14] and (4) there is no evidence talcum powder causes malignant transformation of epithelial cells.[15] Drs. Holcomb and Saenz do not opine on the constituents of talcum powder, including asbestos, fibrous

[9] Holcomb Report at 1.

[10] Holcomb Dep. at 38:14-16; 154:2-4.

[11] *Id.* at 108:16-109:18.

[12] Saenz Report at 4-7; Holcomb Report at 5-7.

[13] Saenz Report at 9-17; Holcomb Report at 7-14, 19-20.

[14] Saenz Report at 17-18; Holcomb Report at 16-17.

[15] Saenz Report at 19-20; Holcomb Report at 17-19.

talc, non-fibrous talc, heavy metals, or fragrances, or whether any of these ingredients can cause or increases the risk of ovarian cancer.

V. DR. SAENZ'S AND DR. HOLCOMBS' OPINIONS ON THE EPIDEMIOLOGY ARE BASED ON FLAWED METHODLOGY AND SHOULD BE EXCLUDED

A. Dr. Saenz and Dr. Holcomb Improperly Value Cohort Studies Above All Other Epidemiology While Ignoring the Totality of the Evidence

Admissibility of an expert's testimony requires more than blind reliance on his or her word alone. *Gen. Elec., Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). An expert must be able to demonstrate that he or she employed a scientifically valid and reliable methodology to form the basis of his or her opinion. Merely stating so is not sufficient.[16] *See Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000) (holding that an expert's *ipse dixit* does not withstand *Daubert's* scrutiny).

[16] *See also Montgomery Cty. v. Microvote Corp.*, 320 F.3d 440, 448 (3d Cir. 2003) (citing Joiner, 522 U.S. at 146); *In re Gabapentin Patent Litig.*, No. *CIV*.A. 00-2931, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011); *Hamilton v. Emerson Elec. Co.*, 133 F. Supp. 2d 360, 370 (M.D. Pa. 2001) ("*ipse dixit* is defined in Black's Law Dictionary as 'a bare assertion resting on the authority of an individual.' Black's Law Dictionary 828 (6th Ed. 1990).").

Nowhere in either Dr. Saenz's[17] or Dr. Holcomb's[18] reports do they explain the methodology they employed in reviewing the epidemiology on the increased risk of ovarian cancer with genital talcum powder use. A proper review requires weighing the totality of the evidence as a whole – not simply reviewing and dismissing studies in isolation or wholesale dismissal or acceptance of studies based on their type without analysis.[19]

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[17] Saenz Dep. at 187:10-25 ("Q. Doctor, can you please point me to the place in your report where you provide for me the methodology that you employed in coming to your expert opinions? A. Ma'am, I already answered this for you. Q. That was your answer? A. Yes, ma'am. Q. In other words, you can't point me to an area in your report where you provide the methodology, can you? A. Ma'am, I already told you, I don't have a specific section titled methodology.").

[18] Holcomb Dep. at 159:22-160:24 ("Q. Doctor, with regard to methodology, will you please point me to the methodology section in your report that informs the reader of the methodology that you employed to render your opinions? A. I would have to point you to my description of the Bradford Hill criteria. Q. Where does that appear? A. I'll find it for you. Page 19. Q. Doctor, is that a methodology section? I asked you specifically if you could point me to the methodology section. A. No. That does – that is not a methodology section. Q. And, in fact, you don't have a methodology section in your report do you? A. I don't have a specific section labeled methodology, no.").

[19] *In re Neurontin Mktg. & Sales Practices Litig.*, 04-CV-10739-PBS, 2011 WL 3852254, at *34 (D. Mass. Aug. 31, 2011), aff'd, 712 F.3d 21 (1st Cir. 2013) (excluding expert's testimony where it was found that the expert "reache[d] his opinion by first identifying his conclusion . . . and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion." (citing *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007))); *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 858 (E.D.N.C. 2015); s*ee also In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449 (E.D. Pa. 2014) (finding expert's opinion not reliable or scientifically sound because the expert failed to account adequately for contrary evidence (citing *In re Avandia*

The epidemiological evidence in this case is robust. There are 37 observational studies of talcum powder and ovarian cancer: 31 case-control studies (7 hospital based and 24 population based), 2 pooled case-control studies, and 4 cohort studies. The overwhelming majority (n=34) of these studies, irrespective of study design, found a positive association (*i.e.*, a hazard ratio > 1), with most showing an association in the range of 1.1-1.7 representing a 10-70% increased risk of ovarian cancer with talcum powder use. In a majority of the published studies (n=19), the positive association reported was statistically significant to a p=.05. However, two of the three cohort studies show no increase in risk of epithelial ovarian cancer. But, interestingly, when the cohort study data is analyzed as a whole, they show an increased risk for serous invasive ovarian cancer.[20]

Although both Dr. Saenz and Dr. Holcomb claimed at their depositions that they conducted a totality of the evidence review of this data, their actual opinions reveal the opposite. Drs. Saenz and Holcomb relied solely on the cohort studies in

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Mktg., Sales Practices & Prod. Liab. Litig., No. 2007-MD-1871, 2011 WL 13576, at *9, 9 (E.D. Pa. Jan. 4, 2011))).

[20] *See* Penninkilampi, Ross, and Guy D. Eslick. 2018, "Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis." *Epidemiology (Cambridge, Mass.)* 29 (1): 41–49, attached hereto as **Exhibit I**. For a complete discussion of the epidemiologic evidence that supports a causal association between genital talcum powder use and ovarian cancer see the *Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions of Defendants' Epidemiology Experts Drs. Ballman, Merlo, Diette & Borak.*

isolation, without consideration of the evidence as a whole.

Dr. Saenz opines that the epidemiology on genital talcum powder use is inconsistent solely because "the cohort studies do not show an increased risk."[21] To arrive at this opinion, Dr. Saenz admits that she failed to weigh the epidemiological evidence in totality and instead, simply valued the results of the cohort studies to the exclusion of all other epidemiology:

> Q. Did you weigh the evidence in your expert report? I didn't see where you had done that.
>
> A. Again, can you –
>
> Q. Did you weigh it in your mind?
>
> A. What do you mean by "weigh"?
>
> Q. So if you looked at say the cohort studies versus the case control studies, did you weigh the case control less heavily than you weighed the cohort studies? Did you put more emphasis on one type of evidence as opposed to another?
>
> A. So I wouldn't use the word weigh. I do believe that the cohort studies have more scientific credibility than the case control studies because the case control studies are subject to more biases and potential confounds than the cohort studies.
>
> Q. You didn't perform a weight of the evidence analysis in your report, did you?
>
> A. No, I did not.[22]

Because she automatically elevated cohort studies above all other epidemiology, Dr. Saenz also rejected the meta-analyses out of hand as "essentially

[21] Saenz Dep. at 309:25-310:4; Saenz Report at 8.

[22] Saenz Dep. at 166:18-167:17.

compilations of the original publications" and "bring[ing] nothing new to the discussion."[23]

Admittedly, because Dr. Saenz did not weigh the totality of the evidence, she never discussed the cohorts' design limitations and weaknesses.[24] Instead, Dr. Saenz based her opinions solely on the results of the cohort studies in isolation because she believes they show no association.[25] Dr. Saenz was required to consider the epidemiology in totality. Her failure to do so resulted in unreliable opinions.

Not surprisingly, Dr. Holcomb's opinion that the epidemiology is inconsistent also is based on his dismissal of all case-control studies and meta-analyses in favor of what he deemed the "higher-level prospective cohort studies."[26] Like Dr. Saenz, Dr. Holcomb believes cohort studies "are considered superior" to the other epidemiology.[27] Based on this flawed understanding, Dr. Holcomb completely dismissed all case-control studies, including those studies that show a statistically significant association, simply because they are case-control studies.[28] Like Dr.

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[23] Saenz Report at 16, 17.

[24] Saenz Report at 13-16; Saenz Dep. at 181:9-13.

[25] Saenz Dep. at 181:22-182:3 ("Q. In formulating your opinions, are they based on the fact that you believe the cohort studies do not show an association between genital talcum powder use and epithelial ovarian cancer? A. That's part of the data that I used to formulate my opinions.").

[26] Holcomb Report at 15.

[27] Holcomb Report at 8.

[28] *Id.* at 15.

Saenz, he also dismissed the meta-analyses as "offer[ing] little new information regarding the association between genital talc use and ovarian cancer."[29]

Dr. Holcomb struggled to find support for his methodology. Dr. Holcomb cited to, and reproduced in his Report, a hierarchy of evidence from the Center for Evidence-Based Management ("CEMB"), a business management website.[30] Dr. Holcomb cherry-picked this hierarchy, not because it is a valid hierarchy for evaluating medical and scientific literature in evidence-based medicine, but because it did what he needed it to do to; it elevated cohort studies above all case-control studies and completely eliminated meta-analyses – something Dr. Holcomb pre-determined was important to his opinions:

> Q. Why did you pick that diagram?
>
> A. I was looking for an example of the – what I believe is a widely held hierarchy on the strengths of different study types based on their ability to be altered by inaccuracies. And this was the diagram that I found that I thought showed it the best.[31]

Finding the hierarchy he needed, Dr. Holcomb ignored the fact that CEMB has nothing to do with medicine.[32] Yet, he opines confidentially that this business

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[29] *Id.*

[30] *Id.* at 8.

[31] Holcomb Dep. at 281:21-282:6.

[32] *Id.* at. at 281:18-20 ("Q. And what – is that a medical site or is that a business site? A. I'm not sure.")).

management hierarchy is "a generally accepted hierarchy" on which doctors should rely and accuses the PSC's experts of "abandoning the well-accepted hierarchy."[33] Dr. Holcomb's opinions are unreliable and not supported by sound methodology.

Tellingly, Dr. Holcomb ignored the hierarchy for evidence-based medicine followed by his own institution Weill-Cornell.[34] Inconveniently for Dr. Holcomb, Weill-Cornell's hierarchy placed meta-analyses at the top and case-control and cohort studies on the same level.[35] Although Dr. Holcomb conceded that contrary to CEMB's business management hierarchy, Weill-Cornell's hierarchy relates to medicine,[36] Dr. Holcomb ignored it because it did not fit his predetermined conclusions. This is entirely unreliable and improper.

Indeed, Dr. Holcomb agreed that cohort studies can be poorly designed.[37] However, like Dr. Saenz, by automatically favoring cohort studies over the case-control studies and meta-analyses, he failed to acknowledge or even consider the cohort's design limitations concerning genital talcum powder use.[38] At his

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[33] Holcomb Report at 7, 9.

[34] Holcomb Dep. at 301:23-303:11 ("Q. So did you look at Weill Cornell's study hierarchy? A. I don't know if – well, no, I don't know that Weill Cornell has a study hierarchy.")).

[35] *Id.* at 304:3-305:15; *see also* Holcomb Dep. Ex. 17, attached hereto as **Exhibit E**.

[36] Holcomb Dep. at 305:19-306:6.

[37] *Id.* at 308:7-17.

[38] *Id.* at 170:20-171:4 ("Q. Did you – you did not present and discuss the study design limitations of the cohort studies, yes or no? A. I'd have to read through the report

deposition, Dr. Holcomb conceded that several design limitations exist with the cohort studies.[39] Dr. Holcomb's failure to consider these limitations to blindly favor cohort studies above all other epidemiology is based on flawed methodology.

The cherry-picking of favorable data and facts "does not reflect scientific knowledge, is not derived by scientific method and is not 'good science.'"[40] "[A]ny theory that fails to explain information that otherwise would tend to cast doubt on that theory is inherently suspect," and "courts have excluded expert testimony" "where the expert selectively chose his support from the scientific landscape"[41] as

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again. I don't remember. Q. You can't answer that question? A. I can't."); *see also* Holcomb Report at 10-12.

[39] Holcomb Dep. at 315:23-317:20; 344:9-21; 376:2-19.

[40] *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 524 F. Supp. 2d at 1176; *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796–800 (3d Cir. 2017) ("An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively chooses his support from the scientific landscape.'"); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 676 (S.D.W. Va. 2014) "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.") *Pooshs v. Phillip Morris USA, Inc.*, 287 F.R.D. 543, 546 (N.D. Cal. 2012) ("A methodology may not be reliable if an expert fails to address and exclude alternative explanations for the data on which he bases his findings or rejects studies reporting contrary empirical findings."); *Abarca v. Franklin Cty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (internal citations omitted)).

[41] *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005).

both Dr. Saenz and Dr. Holcomb have done here. It "is hardly scientific."[42] It is "inherently unreliable."[43] The method used by both Dr. Saenz and Dr. Holcomb are scientifically unreliable cherry-picking. Both experts ignored scientific studies that do not support their opinions. The Third Circuit has deemed expert opinions unreliable where the experts, like Dr. Saenz and Dr. Holcomb, ignored facts of record when formulating their opinions.[44] Thus, their opinions should be excluded.

B. Dr. Saenz and Dr. Holcomb Erroneously Dismiss the Epidemiological Studies that are Unfavorable to their Opinions Based on a Flawed Understanding of Odds Ratios and Statistical Significance

The epidemiological studies related to genital use of talcum powder and ovarian cancer show consistent odds ratios greater than 1.0, with most in the range of 1.2-1.6. The results of the majority of these studies also are statistically significant. Rather than consider this evidence in its totality, Drs. Saenz and

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[42] *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596 (9th Cir. 1996).

[43] *In re Bausch & Lomb, Inc. Contact Lens Solution Prods. Liab. Litig.*, 2009 WL 2760462, at *14 (D.S.C. Aug. 26, 2009).

[44] *See Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d 2000); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002), *aff'd*, 68 F. App'x 356 (3d Cir. 2003) ("in order for an expert's opinions based on evidence to be reliable and admissible, "all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.").

Holcomb improperly parse out studies and reject them based on odds ratios less than 2.0 and a lack of statistical significance. This is not a reliable methodology.

Dr. Saenz dismissed the case-control studies with a statistically significant association simply because they have an odds ratio that is less than 2.0. (Saenz Report at 9; Saenz Dep. at 154:4-14 ("Q. If you look at a body of literature and it's greater than one, and statistically significant, but does not approach a point estimate of 2.0, you deem that weak literature? A. No, I would deem that weak statistical association, a weak odds ratio. Not weak literature, that's not what I said. Q. You deem that a weak association? A. Yes.")). Dr. Saenz opines that the epidemiology does not consistently show an association because "in all of these studies the odds ratio was always below 2.0."[45] Dr. Saenz is unable to cite any authority to support this methodology.[46]

Similarly, Dr. Holcomb conceded that the odds ratios in all but two of the case-control studies are above 1.0. He also acknowledged that the odds ratios of at least two cohort studies are greater than 1.0. (Holcomb Dep. at 206:20-207:20 ("Q. And that body of literature has consistent odds ratios throughout case-control, cohort and – and meta-analyses? A. Cohort, no. I disagree with that. Q. You do? A Yeah. Q. The cohort studies are showing, aside from the Gonzalez study, they are all

[45] Saenz Report at 22.

[46] Saenz Dep. at 155:23-156:5.

showing numbers that are to the right of one, aren't they? For ever[] use? A. For example, Gates is 1.06. Q. Mm-hmm. That's to the right of one, isn't it? A. Yes ma'am. Just right to the right of one."); Holcomb Report at 10 (recognizing Gertig found "[a] modest increased risk was seen for the development of invasive serous ovarian cancer in women reporting any use of talc (relative risk 1.4, 95% confidence interval 1.02-1.91)")).

However, Dr. Holcomb conveniently dismissed case-control and cohort studies based purely on a lack of statistical significance as being "unreliable and attributable to chance," even though their odds ratios are positive and consistent with the statistically significant case-control studies. (Holcomb Dep. at 150:12-19 ("Q. So you created Table 1 to show or to support your claim that the case-control studies were inconsistent based on statistical significance? A. That's fair."); 191:14-18 ("Q. Doctor, is it your opinion that the studies that do not show statistical significance are unreliable and attributable to chance? A: Yes."); Holcomb Report at 20 ("[T]he results of the studies are inconsistent [i]n particular, approximately half of the case-control studies and all of the cohort studies found no significant increased risk of EOC from genital talc use.")). According to Dr. Holcomb, a study's odds ratio must

be greater than 1.0 and statistically significant to have relevance to a causation analysis.[47] However, he is unable to cite any support for this position.[48]

Holcomb's expertise in statistics consists of one statistics class during medical school and things he "learned in reviewing for the – for this deposition."[49] Further, he has no idea who Drs. Rothman and Greenland are and is not familiar with their seminal textbook on epidemiology. One must conclude that his disagreement with these esteemed statistics experts, i.e., that caution dismissing positive odds ratios based solely on statistical significance when reviewing the totality of a body of evidence, is based on his lack of knowledge and understanding of the statistical science.[50]

C. Dr. Saenz and Dr. Holcomb's Dismissal of Case-Control Studies Based on Recall Bias Is Not Based on Sound Methodology

Dr. Saenz and Dr. Holcomb also dismiss all case-control studies based on alleged recall bias supposedly created by the talcum powder litigation but failed to conduct any analysis to determine whether recall bias is actually at play. Their

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[47] Holcomb Dep. at 198:5-22.

[48] *Id.* at 195:13-23.

[49] *Id.* at 284:2-13.

[50] *Id.* at 199:17-22, 219:3-14 (disagreeing with Greenland 2019 article). Dr. Kenneth J. Rothman and Dr. Sanders Greenland are esteemed epidemiologists whose textbook *Modern Epidemiology*, has been relied in by numerous courts including the Third Circuit and has been cited in *Reference Manual on Scientific Evidence. See DeLuca v. Merrell Dow Pharms., Inc.,* 911 F.2d 941, 945, 947 (3rd Cir.1990); *Cook v. Rockwell Int'l Corp.*, 580 F.Supp.2d 1071 (D. Colo. 2006).

opinions in this regard are nothing more than unproven assertions with no evidentiary support or foundation.

Dr. Saenz acknowledges that at least 12 of the case-control studies "demonstrated a statistically significant increased risk of developing ovarian cancer with the ever-use of talc in the perineal area as compared to never users."[51] However, she discredits these findings as completely attributable to recall bias because women with ovarian cancer have been influenced by "the bombardment" of "ubiquitous publicity of talc litigation."[52]

Dr. Holcomb similarly dismisses all case-control studies based on pure speculation about alleged recall bias.[53] He explains that recall bias can occur if you have "an increase in familiarity with a topic that happens after a certain time point and you look at the association before and after this is widely known and show that there's a difference. . . "[54] He acknowledges that people involved in case-control studies likely are not reading the medical and scientific literature on genital talcum powder use, and so are "going to find out about talc . . . through the lay media [and] [t]he lay media pipes up more when there is a product liability associated with it."[55]

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[51] Saenz Report at 9.

[52] *Id.* at 12-13; Saenz Dep. at 304:6-305:12.

[53] Holcomb Report at 8-9.

[54] Holcomb Dep. at 261:24-262:17.

[55] *Id.* at 265:2-266:4.

On this basis, he assumes recall bias from the talcum powder litigation has affected the case-control studies.

Dr. Saenz's and Dr. Holcomb's litigation driven opinions apparently derive purely from their desire to reject the case control studies as a whole. Dr. Saenz admits that she has no idea whether there was widespread media coverage of talc litigation prior to any of the case control studies.[56] Indeed, by Dr. Saenz's own accounting, the vast majority of the case control studies occurred prior to any media coverage of genital talcum powder litigation.[57]

Similarly, Dr. Holcomb admitted that he is unable to opine to a medical degree of probability that recall bias explains the statistically significant increase risk in the case-control studies.[58] That is because Dr. Holcomb has not bothered to determine when widespread media coverage of the talcum powder litigation began.[59]

Instead of conducting any actual analysis of the potential for recall bias, Dr. Saenz and Dr. Holcomb both selectively rely on a single study, Schildkraut et al. 2016, to dismiss all case control studies as being influenced by recall bias. (Saenz

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[56] Saenz Dep. at 305:14-18 ("Q. Do you know when there was the first widespread coverage or media coverage of the talcum powder litigation? A. No, I do not.")).

[57] Saenz Report, Table 2 (showing 29 of 32 case control studies were published prior to potential media coverage in 2014).

[58] Holcomb Dep. at 272:19-273:2.

[59] *Id.* at 266:8-13.

Dep. at 304:24-305:12 (identifying Schildkraut 2016 as demonstrating "that recall bias contributes to the odds ratio"); 311:23-25 ("as evidenced by the Schildkraut study, there's certainly an influence of, on the odds ratio, of recall bias"); 315:1-3 ("I would cite back to Schildkraut, which demonstrated the influence of recall bias, regardless."); Holcomb Dep. at 254:2-22 (identifying Schildkraut 2016 as only study that had "proof" of recall bias); 261:3-15 (citing Schildkraut as demonstrating recall bias "was at play")).

Schildkraut does not support a finding that all case control studies are plagued by recall bias due to media coverage of talcum powder litigation. In contrast to defense representations, what the Schildkraut study authors noted was that "[t]wo class action lawsuits were filed in 2014 concerning possible carcinogenic effects of body powder, which may have influenced recall of use."[60] As a result, the authors assumed there was publicity that led to "heightened awareness of the exposure" but nonetheless, accounted for the potential for recall bias.[61] Notably, the authors concluded that the "data do not support that recall bias alone before 2014 versus 2014 or later would account for the associations with body powder use."[62] The

[60] Schildkraut JM, Abbott SE, Alberg AJ, et al. Association between body powder use and ovarian cancer: The African American Cancer Epidemiology Study (AACES). Cancer Epidemiol Biomarkers Prev. 2016; 25:1411–1417, p. 1415, attached hereto as **Exhibit H**.

[61] *Id.*

[62] *Id.*

authors noted that any potential publicity may not skew the odds ratio because it would have "improved the accuracy of reported use for both cases and controls interviewed in 2014 or later."[63]

Although Schildkraut was able to account for any potential recall bias, the authors' assumptions regarding the first widespread media coverage of the talcum powder litigation were wrong. The first media coverage of any talcum powder litigation occurred in February 2016, when the first large verdict was entered.[64] All case-control studies considered by Drs. Holcomb and Saenz occurred prior to 2016.[65]

For this reason, subsequent studies further discussed why recall bias is not an issue. In the Health Canada draft assessment, the authors noted that recall bias is a potential issue but concluded: "In studies where the exposure is simple (e.g., never versus ever use), recall bias is unlikely to be an important source of bias (Narod 2016). The positive association is strongest for serous histologic type (Berge et al. 2018; Taher et al. 2018); findings that the association may vary by histologic type detracts from the hypothesis of recall bias, as this type of bias would likely operate

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[63] *Id.*

[64] *See Id.* at https://www.usatoday.com/story/money/nation-now/2016/02/24/johnson-johnson-lawsuit-baby-powder-talcum-ovarian-cancer-link/80845030/ (last visited Apr. 22, 2019).

[65] *See* Holcomb Report, Table 1; Saenz Report Table 2. Drs. Holcomb and Saenz did not bother to do this analysis.

for all histologic types (Berge et al. 2018)."[66] Conspicuously, Dr. Saenz failed to include Taher 2018 or the Health Canada assessment in her analysis.[67] Absent an analysis on the issue of recall bias, Dr. Saenz and Dr. Holcomb's opinions regarding recall bias should be excluded.

VI. DR. SAENZ AND DR. HOLCOMB'S OPINIONS ON BIOLOGICAL PLAUSIBILITY ARE BASED ON AN INCORRECT STANDARD OF PROOF AND IGNORE THE TOTALITY OF EVIDENCE

Drs. Saenz and Holcomb's opinions on biological plausibility should be excluded because both experts attempt to impose a heightened burden of proof on Plaintiffs that is improper and misplaced. Plaintiffs are not required to "prove" the mechanism. Biological plausibility does not mean proof of mechanism, but rather whether what is known about the association makes biological sense.

Dr. Saenz opines that biological plausibility requires Plaintiffs to provide "proof" that talcum powder can migrate. She explains that to have biological plausibility "there has to be some ***proof*** that a particulate matter applied to the perineum can actually make it to the ovaries for the hypothesis that talc can cause ovarian cancer to be so." (Saenz Dep. at 197:14-198:2 (emphasis added); 198:11-13 ("there has to be biological evidence that what you're hypothesizing could actually

[66] Health Canada, Environment and Climate Change Canada, "Draft Screening Assessment Talc." Dec. 2018, pp. 28, attached hereto as **Exhibit K**.

[67] Saenz Dep. at 182:5-22.

happen")). Because she says there is no "proof," Dr. Saenz "[c]ompletely disagree[s] with the FDA's position that migration of talc "from the perineum to the vagina and peritoneal cavity is undisputable."[68]

The "proof" that Dr. Saenz says must exist concerning migration, requires an exact study showing talcum powder applied to the perineum of a woman can travel to the ovaries. Dr. Saenz concludes that migration of talcum powder from the perineum to the fallopian tubes or ovaries does not occur because "there's never been a study that's looked at the travel of particulate matter from the perineum to the ovaries."[69] According to Dr. Saenz, without a precise study or "proof," migration and ovarian carcinogenesis do not occur.

Similarly, Dr. Holcomb opines that "it's not [biologically] plausible to me" for talcum powder to migrate from the perineum to the fallopian tubes or ovaries.[70] According to Dr. Holcomb, his "bar is a little bit higher" and so, without a precise study, migration is "not a proven point."[71] Like Dr. Saenz, Dr. Holcomb believes

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[68] *Id.* at 225:7-23; *see* April 1, 2014 FDA letter, attached hereto as **Exhibit J**.

[69] Saenz Dep. at 208:16-25; 218:20-219:1 ("It's my opinion that there's never been anything that has been published in the peer-reviewed literature that shows that something can migrate from the perineum to the ovaries."); Saenz Report at 8 ("There is not a single study demonstrating such migration from the perineum to the ovaries."); Saenz Report at 20 ("There is no literature that particulate matter such as talcum powder, applied to the perineum, can migrate to the ovaries.").

[70] Holcomb Dep. at 422:18-423:7.

[71] *Id.* at 445:12-24.

that you can only conclude that migration occurs if there is a "study where someone dusted the human perineum with talc and showed that it was able to reach the ovary, and that doesn't exist."[72] Without the precise study, Dr. Holcomb also is forced to disagree with the FDA's position that migration is "undisputable"[73] and concludes that "the studies examining this issue do not support plaintiffs' migration theory of biological plausibility."[74]

Applying the wrong "proof" standard, Dr. Saenz also believes that Plaintiffs must provide "scientific proof" in the form of a "mechanistic study that shows that talc leads to ovarian carcinogenesis via chronic inflammation."[75] Based on what she has reviewed, Dr. Saenz does not believe there is any mechanistic data that supports inflammation as a mechanism of carcinogenicity.[76] Without this "proof," she disagrees with the conclusions of study authors that indicate talc can induce chronic inflammation as a mechanism and dismisses them as "hypotheses" rather than statements of fact.[77]

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[72] Holcomb Report at 21; Holcomb Dep. at 129:24-130:4.

[73] Holcomb Dep. at 425:13-426:7.

[74] Holcomb Report at 21.

[75] Saenz Dep. at 234:2-5.

[76] *Id.* at 234:2-5.

[77] *Id.* at 244:8-245:3.

Both experts apply the wrong standard for biological plausibility. The PSC is not required to "prove" the mechanism. Dr. Saenz and Dr. Holcomb confuse proven "mechanism of action" with "biological plausibility." They are distinct in science and under the law. The *Reference Manual on Scientific Evidence* describes biological plausibility as a judgment based on existing knowledge as to whether an agent plausibly could cause an adverse outcome.[78] Biologic plausibility lends credence to an inference of causation.[79] Mechanism of action, on the other hand, explains precisely how an agent causes a disease. The PSC does not have the burden to prove the precise mechanism by which migration and ovarian carcinogenesis occur.[80] *See In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 181 (S.D.N.Y.

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[78] Michael D. Green, *et al., Reference Manual on Scientific Evidence*, at 604-05 (3d Ed. 2011).

[79] *Id.*

[80] *See also In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 149 (D. Mass. 2009) (causation was supported by biologic plausibility notwithstanding the "robust debate in the scientific community" regarding the proposed mechanism); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1247 (W.D. Wash. 2003) ("The fact that the mechanism remains unclear does not call the reliability of the opinion into question."); *In re Avandia Mktg., Sales Practices & Products Liab. Litig*., 2007-MD-1871, 2011 WL 13576, at *4 (E.D. Pa. Jan. 4, 2011); *Rowland v. Novartis Pharm. Corp.*, 149 F.Supp.3d 553, *17 (2014) (defining biological plausibility as a reasonable association between exposure and disease based on what is known about the disease); *In re Fosamax Prods. Liab. Litig*., 2013 WL 155869, *3 (D.N.J. April 10, 2013) (defining biological plausibility as "coherence with existing knowledge"); *Bartoli v. Novartis Pharm. Corp.*, No. CIV.A. 3:13-0724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014) (citing *In re Pfizer Inc. Sec. Litig.*, No. 04CIV.9866(LTS)(JLC), 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010) (allowing testimony regarding biological

2009) ("[b]iologic plausibility is a judgment about whether an agent plausibly could cause a disease, based on existing knowledge about human biology and disease pathology" ... "That the mechanism remains unknown does not mean that the one proposed by the PSC's experts is not widely accepted as plausible."). To require that a mechanism must be proven is mistaken and wrong.[81]

In fact, when applying the correct "plausibility" standard, Dr. Saenz and Dr. Holcomb agree with the PSC that the literature and evidence demonstrates a biologically plausible mechanism. Dr. Saenz concedes that "in terms of biologic

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plausibility "[w]here a 'hypothesis has been deemed plausible and credible in the relevant medical literature' and where it is within an expert's field of expertise based on training, experience, and history of publication.'"); *Wicker v. Consol. Rail Corp.*, 371 F. Supp. 2d 702 (W.D. Pa. 2005) (defining biological plausibility as "coherence with existing knowledge"); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 593 (D.N.J. 2002) (defining biological plausibility as the existence of a biologically plausible mechanism that could cause the adverse outcome of interest); *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489730, at *7–*8 (S.D. Fla. Mar. 19, 2010) (plausible biological mechanism need not be "proven" just "reliable," and using terms of "can" and "may" in regards to such does not render opinion unreliable); *In re Chantix (Varenicline) Prod. Liab. Litig.*, 889 F. Supp. 2d 1272, 1300 (N.D. Ala. 2012) (mechanism theory deemed reliable despite "debate in the scientific community as to whether Dr. Bechara's dopamine depletion theory for Chantix can explain major depression and other neuropsychiatric injuries. . . .debate is not a basis for exclusion"); *In re Hanford Nuclear Reservation Litig.*, No. CY-91-3015-AAM, 1998 WL 775340, at *7 (E.D. Wash. Aug. 21, 1998) (" 'biological plausibility' is not the same as 'biological certainty.'. . . [s]uch certainty cannot be attained.").

[81] *In re Trasylol Products Liability Litigation*, 2010 WL 1489730, at *7–*8.

plausibility, there is some data that there can be particulate matter that can make it to the ovaries" once it gets into the vagina.[82]

Similarly, when asked whether it was his opinion "that there is no biologically plausible mechanism by which talc powder products can translocate or migrate from the perineum to the fallopian tubes and ovaries," Dr. Holcomb explained: "[T]here is no expelling evidence that I've seen that has the ability do it. So I'm not ask – I'm not sure if you're asking is it just possible or is it – is any evidence to suggest that it can happen. Because if – if you're saying is it possible, I'd have to say yes."[83] Drs. Saenz's and Holcomb's inconsistent and contrary opinions regarding biological plausibility are based on an improper standard of proof and should be excluded.

In addition to applying the wrong standard on biological plausibility, Dr. Saenz's and Dr. Holcomb's opinions on biological plausibility should be excluded because they failed to consider the totality of the evidence. Dr. Saenz agreed that it is important to look at the full body of literature in order to make conclusions regarding biological plausibility.[84] However, Drs. Saenz and Holcomb admitted they failed to consider several studies on biological plausibility that are relied on by the

[82] Saenz Dep. at 209:7-14; 217:4-5 ("There is a way that you can pass up through the cervix once something is in the vagina."); 196:5-22 (recognizing that study conclusions regarding migration "are described as plausibility").

[83] Holcomb Dep. at 421:23-422:15.

[84] Saenz Dep. at 173:13-17.

PSC's GYN oncologist experts. (Saenz Dep. at 211:2-11 (hasn't read Sjosten et al. 2004); 213:15-24 (hasn't read Zervomanolakis et al. 2007); 214:8-10 (hasn't read Kunz et al. 1997); Holcomb Depo. at 437:18-22 (did not review Zervomanolakis et al. or Kunz et al.).[85] Drs. Saenz and Holcomb also did not read Dr. Saed's 2019 publication regarding talc and ovarian cancer molecular mechanisms before issuing their opinions.[86] And, neither Dr. Saenz nor Dr. Holcomb informed themselves of the findings in Buz'zard et al. 2007 or Shukla et al. 2009 – two important studies

[85] Sjosten et al., "Retrograde migration of glove powder in the human female genital tract," *Human Reproduction* 19 (4): 991-995 (2004), "pointed out a retrograde migration of starch also in humans after a gynecological examination with powdered gloves" and concludes that "powder or any other potentially harmful substances that can migrate from the vagina should be avoided." *Id.* at 991, attached hereto as **Exhibit L**. *See* Kunz et al., "The Uterine Peristaltic Pump Normal and Impeded Sperm Transport within the Female Genital Tract," *The Fate of the Male Germcell*, Plenum Press (1997), attached hereto as **Exhibit M**; Zervomanolakis et al., "Physiology of Upward Transport in the Human Female Genital Tract," *Ann. N.Y. Acad. Sci.* 1101: 1-20 (2007), attached hereto as **Exhibit N**.

[86] Saenz Dep. at 97:11-21.

relevant to talcum powder causing inflammation that were relied on by the PSC's experts.[87, 88]

The heightened standard that both experts apply is not congruous with the civil law preponderance of evidence standard or with the definition of general causation. Longstanding legal principles govern the standard of proof in a civil case. In the Third Circuit and elsewhere, plaintiff must prove the elements of the claims by a preponderance of evidence. This holds true for evidence of causation, including expert testimony. Plaintiffs are required to prove causation is "more probable than not."[89] "It would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."[90] As the U.S. Supreme Court has recognized, outside the courtroom, it is a fallacy that

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[87] Buz'zard et al., "Pycnogenol reduces Talc-induced Neoplastic Transformation in Human Ovarian Cell Cultures," *Phytother. Res.* 21: 579-586 (2007), attached hereto as **Exhibit O**, demonstrates through *in vitro* data that "talc may contribute to ovarian carcinogenesis in humans by way of inducing aberrant ROS generation." *Id.* at 586. Similarly, Shukla et al., "Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity," *Am. J. Respir. Cell Mel. Bio.* 41: 114-123 (2009), attached hereto as **Exhibit P**, demonstrated that both asbestos and nonfibrous talc caused genotoxicity in exposed mesothelial cells. Despite their clear relevance, Drs. Saenz and Holcomb did not consider either study.

[88] Saenz Dep. at 177:7-12; 178:15-25; Holcomb Dep. at 139:12-18.

[89] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 780 (3d Cir. 1994).

[90] *Daubert,* 509 U.S. at 590. *See also Horan v. Dilbet, Inc.*, 2015 WL 5054856, *13 (D.N.J. Aug. 26, 2015) (noting the unreasonableness of subjecting scientific testimony to a certainty standard).

scientists insist on certainty or near certainty in making judgments. "[M]edical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence."[91] The Third Circuit is clear that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a 'certainty.'"[92]

Nor will such testimony "assist the trier of fact." To the contrary, it will tend to obfuscate and confuse. Opinions that are based on the incorrect legal standard cannot be helpful to the jury and, in fact, create confusion. The very purpose of expert testimony is to help the jury understand the evidence or determine a fact in issue.[93] In its gate-keeper role, the court is tasked with balancing the admission of reliable, helpful expert testimony with the exclusion of that which is misleading or confusing.[94]

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[91] *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 40-42 (2011).

[92] *Horan v. Dilbet, Inc.*, 2015 WL 5054856, *13 (D.N.J. Aug. 26, 2015) (*citing Daubert*, 509 U.S. at 590).

[93] Fed. Rule Evid. 702 (a).

[94] *See Daubert*, 509 U.S. at 595*; In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (3d Cir. 1994) ("[A]dmissibility of scientific testimony turns not only on reliability but also the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury…in conducting this balancing inquiry, there is a presumption of helpfulness.").

Witness testimony couched in the phrases like "it's not plausible to me" and there is no "documented scientific proof" is powerful and resonant.[95] And when uttered from the mouths of experts, this testimony poses a strong risk of misleading the jury to give it undue weight.[96]

The "certainty" testimony is sure to confuse the jury during deliberation because it contradicts the jury instruction that plaintiffs must prove their claims by a preponderance of the evidence. *See Smith v. Ryan,* 813 F.3d 1175, 1199 (9th Cir. 2016) ("If a trained psychiatrist has difficulty with the categorical 'beyond a reasonable doubt' standard, the untrained lay juror—or indeed even a trained judge—who is required to rely upon expert opinion could be forced by the criminal law standard of proof to reject commitment for many patients desperately in need of institutionalized psychiatric care."). Drs. Saenz's and Holcomb's opinions amount to nothing more than a personal pronouncement reflecting their subjective standard for weighing evidence and should not be permitted.

Dr. Holcomb and Dr. Saenz cannot provide coherent opinions on biological mechanism based on an incorrect standard and without consideration of the totality of the evidence. Their opinions should be excluded.

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[95] Holcomb Dep. at 423:6-7; Saenz Dep. at 196:21-22.

[96] *See Nye v. Mistick,* 2015 WL 11511580, *5, n.3 (M.D. Pa. Feb. 24, 2015) (cautioning that experts that exude improper authority can lead juries to give their opinions more weight).

VII. DR. SAENZ'S CRITIQUES OF DR. SMITH-BINDMAN'S EPIDEMIOLOGICAL REVIEW SHOULD BE EXCLUDED

Most of Dr. Saenz's review of the case-control studies is a misguided critique of the PSC's epidemiologist Dr. Rebecca Smith-Bindman.[97] Dr. Saenz is not qualified to criticize Dr. Smith-Bindman and her criticisms are based on *ipse dixit.*

"While the background, education, and training may provide an expert with general knowledge to testify about [a topic], more specific knowledge is required to support more specific opinions." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003). In other words, "[a]n expert may be generally qualified but lack qualifications to testify outside his area of expertise." *Id*. "[A]t a minimum, a proffered expert witness must possess skill or knowledge greater than the average layman." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (quotations and citation omitted).

Dr. Saenz lacks the basic qualifications to critique Dr. Smith-Bindman's epidemiological assessment. Dr. Saenz is not an epidemiologist and does not have any degrees in epidemiology.[98] Her work in epidemiology is limited to review of epidemiological studies in the context of her role as a GYN oncologist.[99]

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[97] *See* Saenz Report at 9-10.

[98] Saenz Dep. at 129:8-11.

[99] *Id.* at 130:4-8.

As a result of her limited epidemiological expertise, Dr. Saenz misunderstands the purpose of the data points reported by Dr. Smith-Bindman and identifies errors where none exist. In Table 1 to Dr. Saenz's report, she purports to show 10 instances where Dr. Smith-Bindman "mis-transcrib[ed] or misquote[ed]" odds ratios and confidence intervals from the case-control studies in Table 4 of Dr. Smith-Bindman's report.[100] Dr. Saenz admits she does not know why the alleged errors exist.[101] Dr. Saenz's accusation that Dr. Smith-Bindman misrepresents the data is the result of Dr. Saenz's own misunderstanding of Dr. Smith-Bindman's epidemiological assessment and the data being reported.

Dr. Saenz assumed Dr. Smith-Bindman intended to report on the data for "ever" versus "never" users of talcum powder. (Saenz Dep. at 114:13-19 ("I am generating this table, extracting the data from the report as published, and comparing it to what Dr. Smith-Bindman listed in her table…forever versus never genital-only use of talcum powder products")).

However, Dr. Smith-Bindman reported on the odds ratios and confidence intervals for daily use, or as close to daily use as possible, when the case control

[100] *Id.* at 110:23-111:13; *see* Expert Report of Rebecca Smith-Bindman (November 14, 2018), attached hereto as **Exhibit F.**

[101] Saenz Dep. at 112:9-13.

studies offered it.[102] Dr. Smith-Bindman did not exclusively provide data on ever versus never talcum powder use. For example, Dr. Saenz states that Schildkraut 2016 reported an odds ratio of 1.44 (1.11, 1.86), not 1.71 (1.26, 2.33) as reported by Dr. Smith-Bindman.[103] However, Schildkraut 2016 reports that for daily use of genital talcum powder the odds ratio is 1.71 (1.26, 2.33).[104] These data points are consistent with those reported by Dr. Smith-Bindman in her Table 4. Dr. Saenz admitted this fact at her deposition. (Saenz Dep. at 119:16-19 (discussing Schildkraut 2016, "Q. And though you didn't report under the result section any genital powder use odds ratio 1.71? A. Because that has to do with daily use.")).

Testimony based on unsupported evidence would only serve to mislead, rather than assist, a trier of fact. *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 176–77 (6th Cir. 2009); Fed. R. Evid. 702. Exclusion is warranted where an expert ignores relevant evidence that would impact her opinions. *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d at 796–800.

Dr. Saenz's failure to understand the purpose of Dr. Smith-Bindman's epidemiological assessment led to Dr. Saenz failing to read the epidemiological

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[102] *See* Feb. 7, 2019 Deposition of Rebecca Smith-Bindman, M.D. ("Smith-Bindman Dep.") at 149:17-150:1, attached hereto as **Exhibit G** (testifying that she "was interested primarily in abstracting data on regular exposure to talcum powder").

[103] Saenz Report, Table 1.

[104] **Exhibit H** (Schildkraut JM, et al. 2016), p. 1414, Table 2.

studies in their entirety to identify the odds ratios and confidence intervals to which Dr. Smith-Bindman was citing. Dr. Saenz's opinions are based on *ipse dixit* and are not helpful, do not assist the trier of fact, and should be excluded.

VIII. CONCLUSION

For this and the other foregoing reasons, the Court should grant the PSC's motion to exclude the report and testimony of Dr. Cheryl Saenz and Dr. Kevin Holcomb from this proceeding.

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